

Appl. No. : 10/614,431
Filed : July 27, 2003

REMARKS

Applicants have canceled pending Claims 93-117 without prejudice to, or disclaimer of, the subject matter contained therein. Applicants maintain that the cancellation of a claim makes no admission as to its patentability and reserve the right to pursue the subject matter of the cancelled claim in this or another patent application.

Applicants have added new Claims 118-155. Applicants maintain that the new claims contain no new matter and are fully supported by the specification as filed. Support for the claims can be found, for example, on page 4, lines 27-29; page 13, lines 12-31; page 14, lines 1-12; page 18, line 21- page 19, line 4; page 13, lines 19-28; page 11, lines 24-25; page 31, page 13, lines 3-10; page 21, lines 25-29; page 24, lines 15-19; page 24, lines 24-25page 25, lines 17-27; page 31, lines 27-29; page 23, lines 4-10; page 26, lines 4- 39; page 5, line 7; page 16, line 9; page 9, line 25; page 22, lines 25-30; in the claims as originally filed, and elsewhere throughout the specification.

On September 13, 2006, the undersigned and Examiner Lankford conducted a personal interview to discuss the Office Action mailed March 30, 2006 and a proposed claim set. During the interview between the undersigned and Examiner Lankford, the indefiniteness rejections 35 U.S.C. § 112, second paragraph, the utility rejections raised under 35 U.S.C. §§ 101, the enablement rejections raised under 35 U.S.C. § 112, first paragraph, and the written description rejections under 35 U.S.C. § 112, first paragraph, raised in the Office Action mailed March 30, 2006 were discussed. The undersigned and the Examiner also discussed proposed claim amendments. The undersigned and the Examiner agreed that a proposed claim directed to a method of processing a cell population that comprises adipose stem cells for reintroduction into a patient, comprising removing adipose tissue that comprises adipose stem cells from said patient; introducing the removed adipose tissue into a self-contained cell processing unit configured to maintain a closed pathway; separating said cell population that comprises said adipose stem cells from non-adipose tissue present in the tissue that was removed from said patient within said self-contained cell processing unit while maintaining said closed pathway; concentrating said cell population that comprises adipose stem cells with said self-contained cell processing unit while maintaining said closed pathway; reintroducing said concentrated cell population that comprises concentrated adipose stem cells from said self-contained cell processing unit into said patient;

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and providing said patient an additional therapeutic agent, would likely overcome the rejections of record.

New Claims 118-155 based on the substance of the interview are now presented for examination on the merits. Applicants respond below to the rejections set forth in the Office Action mailed March 30, 2006. For the reasons set forth below, Applicants respectfully traverse.

Rejection Under 35 U.S.C. § 112, second paragraph - Indefiniteness

The Examiner has rejected Claims 93-117 as allegedly failing to particularly point out and distinctly claim the subject matter of the invention. In particular, the Examiner states that with the exception of Claim 104, while the claims are directed to methods of treatment, the condition to be treated is not clear. Further, the Examiner states that the claims recite a “tissue removal system,” but the system or how it is used is unclear, and that it is also unclear as to whether “system” refers to a method or apparatus. Next, the Examiner requests clarification as to whether the tissue is removed from the same patient to whom the cells are administered. Finally, the Examiner states that the term “stem cells” is indefinite in the context of the rejected claims, since it can refer to several different types of multipotent cells, thereby rendering the scope of the claims unclear.

Applicants have canceled Claims 93-117 and maintain that new Claims 118-155 do not raise the same issues that formed the bases of the Examiner’s rejection of Claims 93-117. Accordingly, Applicants respectfully request that the indefiniteness rejections under 35 U.S.C. § 112, first paragraph, be withdrawn.

Rejection Under 35 U.S.C. § 101 -Utility

The Examiner has rejected Claims 93-101 and 105-117 as allegedly lacking a specific and substantial utility. According to the Examiner, the rejected claims relate to methods of treating a patient, but do not specify the condition to be treated. The Examiner states that a “treatment” without a disclosed desired result cannot be considered a specific and substantial utility.

Applicants have canceled Claims 93-101 and 105-117 and maintain that new Claims 118-155 do not raise the same issues that formed the bases of the Examiner’s rejection of Claims 93-

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101 and 105-117. Accordingly, Applicants respectfully request that the utility rejections under 35 U.S.C. § 101 be withdrawn.

Rejection Under 35 U.S.C. § 112, first paragraph - Enablement

The Examiner has rejected Claims 93-101 and 105-117 under 35 U.S.C. § 112, first paragraph. Specifically, the Examiner asserts that because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility, one skilled in the art would not know how to use the claimed invention.

The Examiner's rejection is based on lack of utility, which Applicants have addressed above. For the reasons set forth in the section addressing the rejection under 35 U.S.C. § 101, Applicants respectfully request that the Examiner reconsider and withdraw the rejection under 35 U.S.C. § 112, first paragraph.

Rejection Under 35 U.S.C. § 112, first paragraph -Written Description

The Examiner has rejected Claims 93-117 under 35 U.S.C. § 112, first paragraph, for allegedly failing to comply with the written description requirement. Specifically, the Examiner argues that the claims relate generically to treating a wide variety of diseases, but that the specification does not demonstrate that Applicants were in possession of the entire scope of the claims.

Applicants have canceled Claims 93-117 and maintain that new Claims 118-155 do not raise the same issues that formed the bases of the Examiner's rejection of Claims 93-117. Accordingly, Applicants respectfully request that the indefiniteness rejections under 35 U.S.C. § 112, first paragraph, be withdrawn.

CONCLUSION

Applicants have endeavored to address all of the Examiner's concerns as expressed in the outstanding Office Action. If the Examiner finds any remaining impediment to the allowance of these claims, the Examiner is respectfully requested to call the undersigned at 619-687-8643 to resolve such issues.

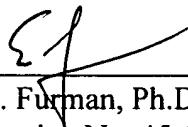
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This action is being filed with a 3-month extension fee. Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: September 29, 2003

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